

# INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

## MEETING MINUTES

**Meeting Date:** Tuesday, September 23, 2025  
**Time:** 3:00 pm Central Time  
**Location:** Zoom Teleconference  
**Institution:** Texas Oncology, P.A. - Austin Midtown, Austin, TX  
**Principal Investigator:** James V.H. Uyeki, MD  
**Protocol:** Genelux Corporation, Olvi-Vec-NSCLC-025  
**NCT Number:** NCT06463665  
**Meeting Type:** Continuing Review of Protocol and Site  
**Title:** A randomized phase 2 study assessing the efficacy and safety of Olvimulogene Nanivacirepvec followed by Platinum-doublet Chemotherapy + physician's choice of immune checkpoint inhibitor compared with Docetaxel in patients with Non-Small-Cell Lung Cancer after first progression while on front-line immune checkpoint inhibitor-based maintenance (VIRO-25 Study)

### 1. Call to order:

The Meeting was called to order at 3:02 pm Central Time.

### 2. Introductions and orientation:

Introductions were made and the Chair oriented members to the meeting procedures.

### 3. Declaration of quorum:

Five voting members were present, including two local members unaffiliated with the institution. Also present were one Institutional Representative and IBC Services staff. The Chair declared that a quorum was present.

### 4. Conflict of Interest:

The Chair requested that voting members report any conflict of interest regarding this meeting. No conflicts of interest were reported.

### 5. Public posting:

The Institutional Representative confirmed that notice of the meeting was publicly posted. No public comments were received by the site or the Committee regarding this review.

### 6. Approval of previous meeting minutes:

Minutes Approved - YES: 5 NO: 0 ABSTAIN: 0

### 7. Review of proposed research:

The Chair provided an overview of the protocol and status of the study.

The Chair provided an overview of changes since the last review.

### 8. Determination for biosafety level and period of IBC oversight:

The Committee previously determined that **BSL-2 containment facilities and practices** are required for Olvi-Vec since it consists of an attenuated, conditionally replicative vaccinia virus administered in a clinical setting. The Committee reaffirmed this determination.

The Committee previously determined that IBC oversight will continue for **6 months after the last subject's last dose of Olvi-Vec locally**, provided that other biosafety criteria for study closure are also met. The Committee reaffirmed this determination.

### 9. Vote on the Protocol:

The Committee voted for the following determination on the Protocol:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 5 NO: 0 ABSTAIN: 0

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### **10. Review of proposed facilities and practices:**

The Chair provided an overview of the arrangement for the facilities and practices.

#### **Points of Discussion:**

1. The Institutional Representative stated that the vortex is not permanently located inside the Biological Safety Cabinet (BSC); it is placed inside the BSC prior to study agent preparation and decontaminated before and after use.
2. The Committee discussed PPE worn by study staff, and the Institutional Representative stated that hair caps are not worn but face shields are. The Committee recommended that site documents be revised to reflect this.
3. The Institutional Representative stated that ethyl alcohol is not used to decontaminate work surfaces. The Committee recommended that Site Inspection Checklist (#19) be revised to indicate this.

### **11. Site requirements:**

The Chair reviewed training and communication requirements for maintaining IBC approval with the Institutional Representative.

### **12. Vote on the Site:**

The Committee voted for the following determination on the Site:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 5

NO: 0

ABSTAIN: 0

### **13. Advice to the Institution:** None.

### **14. Meeting adjourned:** The meeting was adjourned at 3:14 pm Central Time.

### **15. Post-meeting notes:** None.

#### **Documents reviewed:**

Agenda

Protocol, Version 1.2, dated 01-14-2025

Investigator's Brochure, Version 6.6, dated 04-11-2025

Drug Handling Manual, Version 1.1, dated 11-15-2024

Research Modification Evaluation, Protocol, Version 1.2

Research Modification Evaluation, Investigator's Brochure, Version 6.6

Research Modification Evaluation, Drug Handling Manual, Version 1.1

Biological Risk Assessment and Summary, updated 05-14-2025

Site Map, South Austin, dated 08-12-2024

Site Map, Austin Central, dated 09-15-2025

Site Inspection Checklist, expires 08-19-2026, updated 09-15-2025

Photos, Austin Central and South Austin, dated 09-15-2025

Biohazard Sign, dated 06-18-2024

Biosafety Cabinet Certifications, South Austin, expire 11-2025

Biosafety Cabinet Certification, Austin Central, expires 10-2025

SOP, Biosafety for Olvi-Vec, dated 08-29-2025

Training, Shipping Certifications, expire 10-2025, 12-2025, 07-2026, 04-2027

CRRF, dated 06-02-2025

Prior Meeting Minutes, Initial, dated 09-05-2024